Guidance for Industry

Year 2000 Date Change for Computer Systems and Software Applications Used in the Manufacture of Blood Products

This guidance document is being distributed for implementation and comment.

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GUIDANCE FOR INDUSTRY:[1]
YEAR 2000 DATE CHANGE FOR COMPUTER SYSTEMS AND SOFTWARE APPLICATIONS USED IN THE MANUFACTURE OF BLOOD PRODUCTS

I. INTRODUCTION

This guidance document is provided to raise awareness that computer systems and software applications currently used in the manufacture of blood products may experience problems beginning January 1, 2000, due to the use of two-digit fields for date representation.

II. BACKGROUND

In June 1997, FDA issued a letter to medical device manufacturers stating that computer systems and software applications currently used in medical devices may experience problems beginning January 1, 2000, due to the use of two-digit fields for date representation. In addition to adversely affecting the functioning of some devices, the two-digit date format could also affect computer-controlled design, production or quality control processes.

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[1] This document represents FDA's current thinking on the year 2000 date change for computer systems and software applications used in the manufacture of blood products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. Submit written requests for single copies of this document to the Office of Communication, Training and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800, or by fax by calling the FAX Information System at 1-888-CBER-FAX or 301-827-3844. Persons with access to the INTERNET may obtain the document using the World Wide Web (WWW). Connect to CBER at "http://www.fda.gov/cber/guidelines.htm."

To ensure the continued safety and effectiveness of these devices, FDA recommended several courses of action.

For future medical device premarket submissions, manufacturers should assure that the products can perform data recording and computations that will be unaffected by the year 2000 date change.

For currently manufactured medical devices, manufacturers should conduct hazard and safety analyses to determine whether device performance could be affected by the year 2000 date change. If these analyses show that device safety or effectiveness could be affected, then appropriate steps should be taken to correct production and to assist customers who have purchased such devices.

For computer-controlled design, production and quality control processes, manufacturers should assure that two-digit date formats or computations will not cause problems beginning January 1, 2000.

Under 21 CFR 820, *Quality System Regulation*, which became effective June 1, 1997, manufacturers must investigate and correct problems with medical devices that present a significant risk to public health, this includes devices that fail to operate according to their specifications because of inaccurate date recording and/or calculations. Section 518 of the Food, Drug and Cosmetic Act requires notification of users or purchasers when a device presents an unreasonable risk of substantial harm to public health.

III. SPECIFIC RECOMMENDATIONS

A. Users of Blood Establishment Computer Systems and Software Applications

Users of blood establishment computer systems and software applications should contact the manufacturer of these systems to determine the impact that the year 2000 date representation will have on the system software application, database, records, calculations, etc., used in the manufacture of blood products.

A list of those functionalities impacted by design changes made to correct the year 2000 date representation should be obtained from the manufacturer.

All functionalities impacted by design changes made to correct the year 2000 date representation should be validated.

B. Manufacturers of Blood Establishment Computer Systems and Software Applications

Manufacturers should investigate the impact of the year 2000 date representation on blood establishment computer software, and correct any design problems with devices in accordance with the June 1997 letter issued by FDA to medical device manufacturers.

Manufacturers should conduct hazard and safety analyses to determine whether device performance could be affected by the year 2000 date change. Manufacturers should

provide the user with a list of those functionalities impacted by design changes made to correct the year 2000 date representation.

IV. REFERENCES

1. Letter to Medical Device Manufacturers, dated June 25, 1997, from D. Bruce Burlington, Director, Center for Devices and Radiological Health.

2. Quality System Regulation, October 7, 1996, *Federal Register* (61 FR 52602).